

CLAIMS

WHAT IS CLAIMED IS:

1. A system for extracting a bodily fluid sample and monitoring an analyte therein, the system comprising:
 - a disposable cartridge including:
 - a sampling module adapted to extract a bodily fluid sample from a body; and
 - an analysis module adapted to measure an analyte in the bodily fluid sample; and
 - a local controller module in electronic communication with the disposable cartridge, the local controller adapted to receive measurement data from the analysis module and store the data.
2. The system of claim 1, wherein sampling module is adapted to extract an interstitial fluid (ISF) sample and to measure glucose in the ISF sample.
3. The system of claim 2, wherein the sampling module includes:
 - a penetration member configured for penetrating a target site of a user's skin layer and, subsequently, residing in the user's skin layer and extracting an ISF sample therefrom; and
 - at least one pressure ring adapted for applying pressure to the user's skin layer in the vicinity of the target site while the penetration member is residing in the user's skin layer,
 - wherein the sampling module is configured such that the pressure ring is capable of applying the pressure in an oscillating manner whereby an ISF glucose lag of the ISF sample extracted by the penetration member is mitigated.
4. The system of claim 1, wherein the disposable cartridge and local controller are configured to be worn on the body.

5. The system of claim 1 further comprising:
a remote controller module adapted to electronically communicate with the local controller module.

6. The system of claim 5, wherein the remote controller module is configured to receive a glucose test strip and to measure glucose concentration of a blood sample applied to the glucose test strip.

7. The system of claim 5, wherein the remote controller module is adapted to employ a predictive algorithm to predict a blood glucose concentration based on an ISF glucose concentration determined by the local controller module.

8. The system of claim 7, wherein the remote controller module employs an algorithm of the following form:

$$\text{PBGC} = f(\text{ISF}_i^k, \text{rate}_j, \text{ma}_n \text{rate}_m^p, \text{interaction terms})$$

where:

PBGC is a predicted blood glucose concentration;

i is an integer of value between 0 and 3;

j, n, and m are integers of value between 1 and 3;

k and p are integers of value 1 or 2;

ISF_i is a measured ISF glucose value;

rate_j is the rate of change between measured ISF glucose values; and

ma_nrate_m is the moving average rate between averages of groupings of ISF glucose values.

9. The system of claim 1, wherein the sampling module includes:
a penetration member;
a launching mechanism; and
a least one pressure ring.

10. The system of claim 1, wherein the sampling module is adapted to provide a continuous flow of extracted bodily fluid sample to the analysis module.

11. The system of claim 1, wherein the disposable cartridge and local controller module are configured for attachment to the user's skin

12. An interstitial fluid (ISF) extraction device comprising:
a penetration member configured for penetrating a target site of a user's skin layer and, subsequently, residing in the user's skin layer and extracting an ISF sample therefrom; and

at least one pressure ring adapted for applying pressure to the user's skin layer in the vicinity of the target site while the penetration member is residing in the user's skin layer,

wherein the ISF extraction device is configured such that the pressure ring is capable of applying the pressure in an oscillating manner whereby an ISF glucose lag of the ISF sample extracted by the penetration member is mitigated.

13. The ISF extraction device of claim 12, wherein the ISF extraction device is configured such that the pressure ring is capable of applying the pressure in an oscillating manner wherein the pressure is applied for a time period in the range of three seconds to three hours, the pressure is subsequently removed for a time period in the range of three seconds to three hours and then the pressure is re-applied for a period in the range three seconds to three hours.

14. The ISF extraction device of claim 12 further comprising:
at least one first biasing member configured for moving the pressure ring between a deployed state and a retracted state; and
a second biasing member configured for launching the penetration member.

15. The ISF extraction device of claim 12, wherein the penetration member is configured to reside in the user's skin layer for a period of at least 1 hour.

16. The ISF extraction device of claim 12, wherein the at least one pressure ring is a plurality of pressure rings.

17. The ISF extraction device of claim 16, wherein the pressure rings are arranged concentrically.

18. The ISF extraction device of claim 12, wherein the pressure ring and the first biasing element are configured to apply a pressure in the range of 0.1 to 150 pounds per square inch to a user's skin layer.

19. A method for extracting interstitial fluid (ISF), the method comprising:
providing an ISF fluid extraction device that includes a penetration member and at least one pressure ring;
contacting the pressure ring with a user's skin layer;
penetrating the user's skin layer with the penetration member; and
extracting an ISF sample from the user's skin layer with the penetration member while applying pressure to the user's skin layer in an oscillating manner using the pressure ring such that an ISF glucose lag of the ISF sample extracted by the penetration member is mitigated.

20. The method of claim 19, wherein the providing step includes providing an ISF fluid extraction device that includes a plurality of pressure rings.

21. The method of claim 20, wherein the providing step includes providing an ISF fluid extraction device with three concentrically arranged pressure rings.

22. The method of claim 19, wherein the extracting step includes applying pressure in an oscillating manner wherein the pressure is applied for a time period in the range of three seconds to three hours, the pressure is subsequently removed for a time period in the range of three seconds to three hours and then the pressure is re-applied for a period in the range three seconds to three hours.

23. The method of claim 22, wherein the extracting step includes applying pressure in an asymmetric oscillating manner.